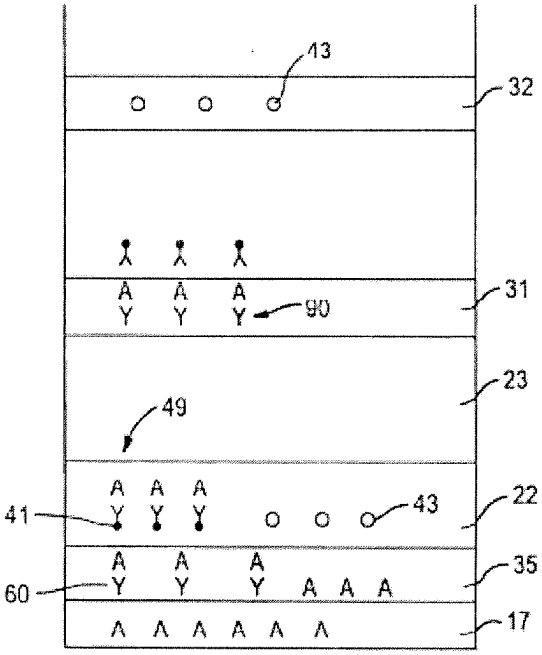
REMARKS

Claims 2, 5-6, 12, and 37-47, including independent claim 37, are currently pending in the present application. To better understand the nature of the claimed invention, reference is made to an embodiment of the present application shown in Fig. 3, a portion of which is reproduced below.



In this embodiment, a test sample containing an analyte A is initially contacted with a sampling pad 17. At the sampling pad 17, a certain quantity of the analyte A binds to a first capture reagent 60 immobilized at the scavenging zone 35, such as an amount less than or equal to a predefined base quantity of analyte considered "normal" for the particular test sample. From the sampling pad 17, any analyte A in excess of the predefined base quantity travels to the conjugate pad 22, where it mixes with conjugated detection probes 41 and calibration probes 43. The excess analyte A binds with the conjugated detection probes 41 to form analyte/conjugated probe complexes

49. Because the conjugate pad 22 is positioned downstream from the scavenging zone 35, however, it is not necessary to supply detection probes 41 for binding to any of the analyte A that is already captured by the scavenging zone 35. In this manner, the overall amount of required probes is reduced, which provides substantial cost savings. At the detection zone 31, the complexes 49 are captured by a second capture reagent 90. Once captured, the signal of the probes at the detection zone 31 and calibration zone 32 may be measured using any known method of detection, such as visually or with a reading device.

In the Office Action, independent claim 37 was rejected under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent No. 6,509,196 to Brooks, et al. in view of U.S. Patent No. 6,258,548 to Buck. Brooks, et al. describes a membrane strip that includes an application point, a contact region, and a detection zone. The contact region includes test particles coated with a binding agent for the analyte (e.g., an antibody) that can move through the strip and bind to a reagent in the detection zone. To provide an approximation of the amount of non-specific reaction of the test particles, the contact region also includes internal control particles coated with a binding agent that is *not specific* for the analyte. The internal control particles also move through the strip and can bind to a reagent in a control zone. However, the binding agent of the control particles is not specific for the analyte, such as an antibody that binds to an antigen that is uninvolved in the assay.

In Example 1 of Brooks, et al., for instance, the test particles are coated with a mouse monoclonal antibody that is specific for a myoglobin analyte. On the other hand, the internal control particles are coated with mouse monoclonal antibody MOPC31-c,

which has an unknown specificity for myoglobin. According to Brooks, et al., the purpose of using such internal control particles, which are not specific for the analyte, is to determine the amount of "non-specific binding" that occurs during the assay. As correctly noted by the Examiner, however, Brooks, et al. fails to disclose numerous limitations of independent claim 37. For example, Brooks, et al. completely fails to disclose the claimed "scavenging zone."

The Office Action attempts to cure the deficiencies noted above by combining Brooks, et al. with Buck. Buck is directed to a sandwich format assay that may include an analyte modulating zone ("AMZ"). According to the Office Action, it would have been obvious to use the analyte modulating zone of Buck to determine an optimum quantity of analyte for detection and then use the AMZ to remove excess analyte for reaching this quantity. However, one of ordinary skill in the art having common sense at the time of the invention would not have reasonably looked to Buck to solve the problem of excess analyte when that was not even a problem in Brooks, et al. Respectfully, the claimed invention taken as a whole is not obvious when considering the references in their entirety.

Regardless, even if the references are somehow combined, they still fail to disclose various features of the present claims. Dependent claim 41, for example, requires that the first capture reagent (scavenging zone) and the second capture reagent (detection zone) both include antibodies that bind to the same epitope of the analyte. Thus, should any of the first capture reagent somehow become free from the scavenging zone and travel to the detection zone, it will not bind to the second capture reagent and adversely impact the desired reduction in detection sensitivity. Neither

Brooks, et al. nor Buck discloses this feature. Example 1 of Buck, et al. is illustrative of this point. In the Example, a pregnancy test strip was made to test for the presence of hCG. The test line contained anti-α hCG antibody and the AMZ contained anti-β hCG antibody. Thus, as indicated, the capture reagent used in the test line is specific to the α-epitope of hCG, while the capture reagent used in the AMZ is specific to the β-epitope of hCG.

Thus, for at least the reasons indicated, Applicants respectfully submit that the present claims patentably define over the cited references, taken singularly or in any proper combination. It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

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4/7/09
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